21 CFR Part 800

[Docket No. 82N-0332]

Tamper-Resistant Packaging Requirements for Contact Lens Solutions and Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its tamper-resistant packaging and labeling regulations for contact lens solutions and for tablets and other dosage forms used to make such solutions. The amendments clarify the regulation and conform it to amendments made elsewhere in this issue of the Federal Register to the tamper-resistant

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packaging and labeling regulations for certain over-the-counter drugs and cosmetics.

EFFECTIVE DATE: April 19, 1983.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, National Center for Devices and Radiological Health (HFK-140), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 5, 1982 (47 FR 50452), FDA published a regulation (21 CFR 800.12) establishing tamper-resistant packaging and labeling requirements for solutions intended for use with contact lenses, e.g., for cleaning, disinfecting, wetting, lubricating, rinsing, soaking, or storing contact lenses, and for tablets to be used to make any such solution. FDA published corrections in the Federal Register of January 14, 1983 (48 FR 1706).

FDA received no comments on the tamper-resistant packaging and labeling regulation. The agency is, however, making the following changes in the regulation:

1. As in the regulations applicable to certain drugs and cosmetics, also amended in this issue of the Federal Register, FDA is clarifying that the tamper-resistant packaging and labeling requirements apply only to products that are accessible to the public while held for sale. Thus, contact lens products sold only through health professionals such as ophthalmologists and optometrists are not subject to these requirements.

2. As in the drug and cosmetic regulations, the agency is adding an explanation of the term "distinctive by design" and is giving examples of "an identifying characteristic." These terms are found in the requirement in § 800.12(b) that the required indicator or barrier to entry by "distinctive by design or by the use of an identifying characteristic."

3. As in the drug and cosmetic regulations, the agency is clarifying the requirement for labeling alerting consumers to the tamper-resistant feature of the package.

4. The agency also is applying the regulation to any dosage form used to make contact lens solutions (e.g., salt capsules), as well as to tablets, if the product is accessible to the public while held for sale. This amendment takes into account the possibility of new types of products to which the regulation might need to apply.

Accordingly, the regulation is amended as described above.

Interpretations of the tamper-resistant packaging and labeling regulations found in the preamble to the amendments that are being published to the regulations for certain over-the-counter drugs and cosmetics also apply to § 800.12.

In the preamble to the November 5, 1982 final rule, the agency discussed the economic considerations of the rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (47 FR 50454). The agency concluded that the costs of conversion to tamper-resistant packaging would not be sufficient to warrant designation of the rule as a major rule under Executive Order 12291 and, further, certified under the Regulatory Flexibility Act that the rule will not have a significant economic impact on a substantial number of small entities.

These amendments to the final rule are for clarification. The agency finds that the regulatory impacts previously considered are not changed to any measurable degree and, accordingly, reexamination of the economic impacts under Executive Order 12291 and the Regulatory Flexibility Act is not necessary.

The agency has determined pursuant to 21 CFR 25.24(d)(13) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 800

Administrative practice and procedure, Medical devices.

PART 800—GENERAL

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 501, 502, 515, 521, 701, 52 Stat. 1041 as amended, 1049–1051 as amended, 1055–1056 as amended, 90 Stat. 552–559, 574 (21 U.S.C. 321(n), 351, 352, 360e, 360k, 371)) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 800 is amended in § 800.12 by revising paragraphs (a), (b), and (c), to read as follows:

§ 800.12 Contact lens solutions and tablets; tamper-resistant packaging.

(a) *General.* Unless contact lens solutions used, for example, to clean, disinfect, wet, lubricate, rinse, soak, or store contact lenses and salt tablets or other dosage forms to be used to make any such solutions are packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of these products with risks both to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of the packages of over-the-counter (OTC) health care products. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national standard for tamper-resistant packaging of those OTC products vulnerable to malicious adulteration that will improve the security of OTC packaging and help assure the safety and effectiveness of the products contained therein. A contact lens solution or tablet or other dosage form to be used to make such a solution for retail sale that is not packaged in a tamper-resistant package and labeled in accordance with this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages for retail sale a product regulated as a medical device that is a solution intended for use with contact lenses, e.g., for cleaning, disinfecting, wetting, lubricating, rinsing, soaking, or storing contact lenses or tablets or other dosage forms to be used to make any such solution shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the package cannot be duplicated with commonly available material or through commonly available processes. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a product covered by this section is required to bear a statement that is prominently placed so that consumers are alerted to the tamper-resistant

feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

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Effective date. April 19, 1983.

(Secs. 201(n), 501, 502, 515, 521, 701, 52 Stat. 1041 as amended, 1049–1051 as amended, 1055–1056 as amended, 90 Stat. 552–559, 574 (21 U.S.C. 321(n), 351, 352, 360e, 360k, 371))

Dated: March 17, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

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